

Application Serial No. 10/628,974  
Response dated June 24, 2005  
Reply to Office Action dated April 25, 2005

## **REMARKS**

Claims 1-12 are pending. Claims 1-12 are rejected in the present Office Action. No claims are presently amended. In view of the discussion below, Applicant believes that the application is in condition for allowance.

### **Claim Rejections 35 U.S.C. § 112**

Claims 1-12 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.<sup>1</sup> In particular, Examiner states that there is no support in the application for the language in claim 1 reciting a second moveable member that can be "repeatedly" moved between retracted and extended positions, and in claim 7 reciting a member that can be "returnable" to the extended position after being returned to the retracted position. Applicant respectfully disagrees.

While the words "repeatedly" and "returnable" do not appear verbatim in the text of the application as filed, Applicant submits that support does exist for those terms. In particular, and referring to Fig. 1, the specification as originally filed describes a port access system 100 for providing fluids to a patient. The system includes a housing 110 having a port 120, a first moveable member 122 (such as a needle), and a second moveable member 130 coupled to the first moveable member. The second moveable member is biased (by spring 140) to a retracted position wherein the needle is not in fluid communication with the port. The second moveable member can be

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<sup>1</sup> In rejections under both 35 U.S.C. §§ 112 and 103, Examiner states that claims 1-14 are rejected. Applicant believes this is a mistake on the part of Examiner in that only claims 1-12 are pending in the application. Thus, Applicant only discusses the rejection of claims 1-12.

Application Serial No. 10/628,974  
Response dated June 24, 2005  
Reply to Office Action dated April 25, 2005

moved from the retracted position to an extended position ("The needle is activated by pressing down on the second moveable member 130, which then allows infusion of the needle with a channel built into the device." Para. 0028). Upon release, the second moveable member and needle are biased by the spring to return to the retracted position ("Spring 106 returns to its relaxed position and pushes second moveable member 130 back to its deactivated position." Para. 0031). The specification thus describes a second moveable member that moves from a retracted position to an extended position, and then moves from the extended position back to the retracted position, which is repeated movement. The foregoing thus describes that the second moveable member "repeatedly move[s] between a retracted position... and an extended position," as recited in claim 1.

Further, once the member moves from the extended position to the retracted position, it can be in its original retracted position. There is no requirement that there not be reactivation of the moveable member to move it, again, to the extended position after it has been returned to the retracted position. Nor is there any specific disclosure that such reactivation is prohibited. Thus, as regards the invention of claim 7, a user may simply press the moveable member in a downward position to again reextend the member and have it then returned again to the retracted position upon release. Claim 7 does not require that the moveable member be returned to the extended position after being returned to the retracted position. It only requires that the moveable member be "returnable" to the extended position. That is clearly possible

Application Serial No. 10/628,974  
Response dated June 24, 2005  
Reply to Office Action dated April 25, 2005

with the structure of the described apparatus. Thus, the moveable member is "returnable to the extended position after being returned to the retracted position," as recited in claim 7.

In view of the above, Applicant respectfully submits that the rejections of claims 1-12 under 35 U.S.C. § 112, first paragraph, are in error and should be withdrawn.

**Claim Rejections 35 U.S.C. § 103**

Claims 1-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cirelli (U.S. Patent No. 5,848,990) in view of Dysarz (U.S. Patent No. 5,935,113). Applicant respectfully disagrees with the rejection and submits that one skilled in the art would not be motivated to combine Cirelli and Dysarz to reach the invention of either independent claim 1 or independent claim 7 because to do so would require an unwarranted modification of Cirelli, and would render useless certain components of Cirelli.

Examiner points to Cirelli as disclosing an apparatus having an adhesive layer 4 (which Examiner calls "wings with adhesive") to hold a cannula 9 (which Examiner calls a "needle cannula") to a patient's skin, a channel 11 in a cannula holder 10 (which Examiner calls a "moveable member") that can be repeatedly moved between retracted and extended positions (and coupled to the cannula 9 in order to prohibit fluid flow when the cannula holder 10 is in the retracted position), and a luer attachment 6 (which Examiner calls an "intravenous line") in order to connect the

Application Serial No. 10/628,974  
Response dated June 24, 2005  
Reply to Office Action dated April 25, 2005

cannula to a reservoir of fluid to be delivered to the patient. Examiner points to Dysarz as disclosing an apparatus having an elongated capsule 9 (which Examiner calls a "housing"), a hard cannula 37 (which Examiner calls a "moveable needle"), a piston base 27 (which Examiner calls a "second moveable member"), a spring 25, a piston stop 13 (which Examiner calls a "retention mechanism"), and a latch bar 8 (which Examiner calls a "trigger") for activating a release mechanism. Examiner states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Cirelli such that it included the use of a spring, retention mechanism, and trigger for activating a release mechanism in view of the teachings of Dysarz. Applicant respectfully disagrees.

Claim 1 recites that the apparatus includes "a spring coupled to the housing and the second moveable member to bias the second moveable member to the retracted position." Examiner acknowledges that Cirelli does not include such a spring, because the spring provided in Cirelli biases the cannula holder to the extended position, which is the opposite of what Applicant claims. [For example, at column 4, lines 4-11, and referring to Fig. 1, Cirelli discloses that a spring 17 is positioned adjacent the cannula holder 10 (i.e., a movable member) and biases the cannula holder 10 toward the base of housing 1 (i.e., the "extended" position).] So Examiner looks to Dysarz to provide a spring to bias to the retracted position.

However, Applicant asserts that one skilled in the art would not combine the spring of Dysarz with the Cirelli apparatus. If one were to add the spring of Dysarz

Application Serial No. 10/628,974  
Response dated June 24, 2005  
Reply to Office Action dated April 25, 2005

to the apparatus of Cirelli, one would have two springs operating in opposition without any apparent structure to allow them both to work. In other words, such an apparatus would include a spring (from Cirelli), and a second spring (from Dysarz) biasing the cannula holder toward and away from the patient at the same time. Such a configuration would make no sense, and certainly would not have been an obvious thing to do.

Nor is there any motivation, or reason, to replace the spring of Cirelli with that of Dysarz, except Applicant's own teaching. Further, even if one were so motivated without the benefit of Applicant's disclosure, such motivation would result in a wholesale modification of Cirelli that destroys the function of Cirelli: namely that the spring of Cirelli is configured to use spring bias to quickly drive the cannula to the extended position and into a patient so the patient feels no discomfort (See column 4, lines 56-58). By contrast, the spring of Dysarz is configured for a completely different purpose. The apparatus of Dysarz is adapted for a single use, and thus Dysarz is configured to bias the needle to be retracted into the elongated capsule, where it cannot be reextended, thereby preventing inadvertent needle sticks. Due to the different purposes of Cirelli and Dysarz, the different configurations resulting therefrom, and the unwarranted modifications one would have to engage in to reach an apparatus that destroys a function of Cirelli, Applicant asserts that one skilled in the art would not be motivated to combine the teachings of Cirelli and Dysarz to reach the invention of claim 1.

Application Serial No. 10/628,974  
Response dated June 24, 2005  
Reply to Office Action dated April 25, 2005

Claim 7 recites that the apparatus includes "a retention mechanism to secure the moveable member in said extended position" and "a release mechanism to release the moveable member from the retention mechanism to allow the moveable member to return to a retracted position." Examiner acknowledges that Cirelli does not include such a retention mechanism and release mechanism because the retention mechanism provided in Cirelli secures the cannula holder in the retracted position (rather than in the extended position as claimed by Applicant), and the release mechanism allows the moveable member to move to an extended position (as opposed to moving to the retracted position as presently claimed).

Even assuming that Dysarz includes a retention mechanism and a release mechanism, such as the piston stop 13 (which Examiner calls "a retention mechanism") and the latch bar 8 (which Examiner calls "a trigger for a release mechanism"), there is no motivation or suggestion to provide them in Cirelli. This is because the Cirelli apparatus is not designed to be retained in the extended position and release to the retracted position. Rather, Cirelli discloses that its retaining and releasing mechanism 14 retains the cannula holder 10 (i.e., the moveable member) in the resting state in a retracted position and, by releasing, permits displacement into an extended position. This design is in accordance with the purpose of Cirelli, which is to hold the cannula in the retracted position, and when released, to quickly spring out to the extended position into a patient such that the patient feels no discomfort (See col. 4, lines 56-58). And the needle already stays out until retracted. Thus, Cirelli does not require further

Application Serial No. 10/628,974  
Response dated June 24, 2005  
Reply to Office Action dated April 25, 2005

mechanisms for retaining the cannula in the extended position and releasing to the retracted position since Cirelli has no purpose that would require such structure. And so there would be no motivation to add such mechanisms. Merely because Dysarz might have structure to operate to hold the needle extended is of no consequence since there is nothing to warrant its inclusion in the device of Cirelli.

The Federal Circuit made clear in Ruiz v. A.B. Chance Co., 69 U.S.P.Q.2d 1686, 1690 (Fed. Cir. 2004), that, in making the assessment of differences between the prior art and the claimed subject matter, section 103 specifically requires consideration of the claimed invention "as a whole." In that regard, it is recognized that inventions are typically new combinations of existing principles or features. Environmental Designs, Ltd. V. Union Oil Co., 218 U.S.P.Q. 865, 870 (Fed. Cir. 1983) (noting that "virtually all [inventions] are combinations of old elements."). The "as a whole" instruction in title 35 prevents evaluation of the invention part by part. Ruiz, 69 U.S.P.Q.2d at 1690. Without this important requirement, an obviousness assessment might successfully break an invention into its component parts, then find a prior art reference corresponding to each component. Id. Such an approach would import hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components. Further, this improper method would discount the value of combining various existing features or principles in a new way to achieve a new result – often the essence of invention. Id.

Application Serial No. 10/628,974  
Response dated June 24, 2005  
Reply to Office Action dated April 25, 2005

Contrary to such reasoning, section 103 requires assessment of the invention as a whole. Id. This "as a whole" assessment of the invention requires a showing that an artisan of ordinary skill in the art at the time of the invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the various elements from the prior art and combined them in the claimed manner. Id. In other words, section 103 requires some suggestion or motivation, before the invention itself, to make the new combination. See In re Rouffet, 47 U.S.P.Q.2d 1453, 1457-1458 (Fed. Cir. 1988).

Nor is there any motivation or reason to replace the retention and release mechanisms of Cirelli with those of Dysarz. First, the only motivation to do that comes from Applicant's own teaching. Further, even if one were so motivated without the benefit of Applicant's disclosure, such motivation would result in a wholesale modification of Cirelli that destroys the function of Cirelli: namely, as described above, that the retention and release mechanisms of Cirelli are configured to initially hold the cannula out of contact with the patient, and, release to extend the cannula into the patient quickly so that the patient feels no discomfort. By contrast, the retention mechanism and release mechanism of Dysarz is configured for a completely different purpose. The apparatus of Dysarz, as described above, is configured to release the needle to move from an extended position (where it is initially retained) to a retracted position in the elongated capsule so it cannot be reextended, thereby preventing inadvertent needle sticks. Thus, replacing the retention and release mechanism of



Application Serial No. 10/628,974  
Response dated June 24, 2005  
Reply to Office Action dated April 25, 2005

Cirelli with those of Dysarz results in an apparatus (1) that destroys the purpose of Cirelli by destroying the function of quickly extending a cannula into a patient, and (2) wherein the moveable member is not returnable to the extended position after it has been returned to the retracted position. Due to the different purposes of Cirelli and Dysarz, the different configurations resulting therefrom, and the unwarranted modifications one would have to engage in to reach an apparatus that destroys a function of Cirelli, Applicant asserts that one skilled in the art would not be motivated to combine the teachings of Cirelli and Dysarz to reach the invention of claim 7.

For the foregoing reasons, claims 1 and 7 of the present application are not rendered obvious by Cirelli in combination with Dysarz. For at least the same reasons, claims 2-6 (dependent from claim 1) and claims 8-12 (dependent from claim 7) are also not rendered obvious by Cirelli and Dysarz.<sup>2</sup> Therefore, Applicant respectfully submits that the rejections of the claims under 35 U.S.C. § 103 are in error and should be withdrawn.

### **Conclusion**

It is believed that all claims are allowable, and a Notice of Allowance is respectfully requested.

No fee is believed due. If any fee or surcharge is deemed due, please charge Deposit Account No. 23-3000.

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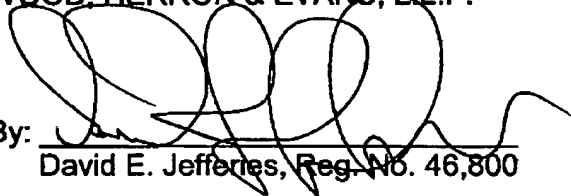
<sup>2</sup> Under the circumstances, Applicant does not address the dependent claims separately, but reserves the right to do so should the need arise.

Application Serial No. 10/628,974  
Response dated June 24, 2005  
Reply to Office Action dated April 25, 2005

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,

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